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10/757,047	01/14/2004	Heinrich Kladders	1/1449	4842
28501 7590 02/22/2008 MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877-0368				
EXAMINER				
ALI, SHUMAYA B				
ART UNIT		PAPER NUMBER		
3771				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/757,047

**Applicant(s)**

KLADDERS ET AL.

**Examiner**

SHUMAYA B. ALI

**Art Unit**

3771

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/15/08 has been entered.

### ***Status of Claims***

2. Claims 1-20 are pending in the instant application.

### ***Claim Objections***

3. Claim 1 is objected to because of the following informalities: in line 2, the recitation of "capsule comprising" is not a proper method step to limit capsule structure recited in lines 3-11. If Applicant wants to claim method steps using a particular capsule then Applicant is strongly suggest to use --providing a capsule-- instead of "capsule comprising". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the features", "the outer contour of the capsule" in line 5, "fine structures of any seams in line 8, "the individual parts" in lines 8 and 9, "elements formed on the capsule surface" in line 10, and "angles of taper up to 5" degrees in line 11. There are insufficient antecedent basis for these limitations in the claim. In line 5 the term "the outer contour of the capsule" lacks proper antecedent basis. The phrase in lines 8-11 is confusing because it is not clear whether the features being excluded from the conditions of symmetry are part of the invention. In addition, in lines 8-11, it is not clear what is structural relationship between the "fine structures of any seams", "individual parts", "elements formed on the capsule surface", "angle" and the claimed method, furthermore, location of these structures is not clear. In lines 1 and 2 Applicant claims "A method for administering a composition" however, does not lay out proper method steps for administering said composition in the body of the claim. In line 8 "fine structures...which are produced by the sealing of the seams" is unclear as to whether the invention is directed to method of administering a composition or method of making a capsule. It appears that Applicant is combining method of using (i.e., a composition by inhalation") and method of making (i.e., sealing seams on capsule) in the same claim, which is improper. The second recitation of "and/or" in line 10. It is not clear as whether the limitation after "and/or" only applies to "elements formed on the capsule surface" as in line 10, or also applies to the "individual parts of the capsule" in line 9.

Claims 2-15 are indefinite because there are no method steps being cited.

In claim 2, "wherein the inhaler is a Bernoulli inhaler" is indefinite. Applicant is claiming an apparatus without establishing a proper step of using the apparatus in a method claim.

In claim 3, it appears that the Applicant attempted to redefine the structure of the capsule, which is indefinite because criteria for symmetry giving a particular shape and size of the capsule has been established in claim 1.

In claim 5 line 1 "the capsule has not elevations" is indefinite. Location of these elevations is not clear.

In claim 16, the limitations "the features" and "the outer contour" in line 6, "the fine structures of the seams" in line 8, "the individual parts" and "the pharmaceutical capsule" in line 9, "elements formed on the capsule surface which are smaller than 0.1 mm" and "angles of taper up to 5" degrees in lines 9 and 10 lack antecedent bases. In line 1 recitation "An inhaler for administering a composition" and in line 8 "produced by the sealing of steams" are confusing because it appears Applicant is claiming method of making capsule structure in an apparatus claim, which is improper. The second recitation of "and/or" in line 10 is indefinite. It is not clear whether the limitation after "and/or" only applies to "elements formed on the capsule surface" in line 9, or also applied to "individual parts of the capsule" in line 9.

In claim 17 line 1, it is not clear to which disclosed part that the "which" is being referred. Furthermore, the limitations "the closed" in line 1, "the features" and "the outer contour" in line 4, "the fine structures of the seams" in line 6, "the individual parts" in line 7, "elements formed on the capsule surface which are smaller than 0.1 mm" and "angles of taper up to 5" degrees in line 8 lack antecedent bases. In line 1 recitation "A capsule for holding a pharmaceutical composition" and in line 7 "produced by the sealing of steams" are confusing because it appears Applicant is claiming method of making capsule structure in an apparatus claim. The second recitation of "and/or" in line 8 is confusing because it is not clear whether the

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limitation after “and/or” only applies to “elements formed on the capsule surface” in line 8, or also applies to “individual parts of the capsule” in line 7.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1, 4-9, and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Hochrainer et al. US 2001/0008637 A1.**

**As to claim 1**, Hochrainer US'637 discloses a method for administering a composition by inhalation comprising administering to a patient the composition, contained in a capsule (1). Figure 2a of Hochrainer shows a longitudinal axis and a transverse axis which is shorter in relation to the longitudinal axis. In paragraph 2 lines 2-4 Hochrainer US'637 discloses the capsule can be used in a powder inhaler, thus capsule (1) inherently accommodates the composition in the form of a powder. Figure 2a of Hochrainer further shows the outer contour of the capsule are symmetrical with respect to a transverse plane which bisects the longitudinal axis, except for angles of taper up to 5° (see bulge 5) on the body (3) of capsule, which however is one of the features excluded from the conditions of symmetry in the claimed invention.

**As to claim 4**, Hochrainer US'637 in figure 2a shows the outer surface/body of the capsule (3) has elevations formed by bulge (5).

**As to claim 5**, Hochrainer US'637 in figure 2a shows the outer of cap (2) has no elevations.

**As to claim 6**, Hochrainer US'637 in figures 1-8 shows the capsule consists of two parts, cap (2) and body (3). Hochrainer US'637 in paragraph 2 line 6 and paragraph 17 lines 1-3 discloses parts of the capsule can be pushed telescopically one inside the other along the longitudinal axis.

**As to claim 7**, Hochrainer US'637 in paragraph 22 line 2 discloses the capsule has cylindrical shape. Figures 1-8 also show the capsule has a cylindrical outer contour.

**As to claim 8**, Hochrainer US'637 in paragraph 29 lines 1-3 discloses the bulge (5) which tapers, which provides tapering sealed ends for the capsule.

**As to claims 9 and 18**, Hochrainer US'637 in paragraph 29 lines 5-7 discloses that in the closed position of the capsule, the edge does not project beyond the cap (2), thus providing a flat transition from the cap (2) to the body (3), thus there is inherently zero percent offset of the outer longitudinal length when the two parts of the capsule are closed by seam.

**As to claim 17**, Hochrainer US'637 in paragraph 2 line 6 and paragraph 17 lines 1-3 discloses parts of the capsule can be pushed telescopically one inside the other along the longitudinal axis.

#### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l) (1) and § 706.02(l) (2).

9. **Claims 2, 3, 10, 19, and 20 are rejected under 35 U.S.C. 103(a) as being obvious over Hochrainer et al. US 2001/0008637 A1.**

As to claim 2, Hochrainer US'637 lacks inhaler is Beroulli inhaler. However Applicant on page 3, lines 26-28 of his disclosure states that powder inhaler operate by the Bernoulli effect,



which behave identically irrespective of their positioning. Since Hochrainer US'637 in paragraph 2 line 4 teaches the capsule is used a power inhaler, this inhaler is considered Bernoulli inhaler.

**As to claims 3 and 20**, Hochrainer US'637 does not explicitly teaches claimed tolerance and inaccuracy. However, figure 2a of Hochrainer shows the outer contour of the capsule surface and forming a symmetrical pair and bulge portion (5) "may" have a tolerance and inaccuracy deviation from the symmetry of 0.15 mm in each cases.

**As to claims 10 and 19**, Hochrainer US'637 in figures 1-8 shows the two parts of the capsules are not mirror image, rather have projection (7) and bulge (5) on the outer contour of one part, which make the capsule a member of the D-symmetry group. When sealing the capsule it is obvious that its manufacturing tolerance would deviate the capsule parts from having mirror symmetry since it is well known in manufacturing.

**10. Claims 11-15 are rejected under 35 U.S.C. 103(a) as being obvious over Hochrainer et al. US 2001/0008637 A1 in view of Hochrainer et al US 5,947,118.**

**As to claim 11**, Hochrainer US'637 lacks detailed structure of the inhaler. However, Hochrainer US'118 in figure 6 and in column 3 lines 1-17 teaches an inhaler comprises two housing parts, an upper housing part (13) which is connected to a mouthpiece (12), and a lower housing part (6) with at least one capsule chamber (9), the capsule chamber(s) having an air inlet opening (14), and an air outlet opening (though mouthpiece 12) connected to the mouthpiece via a connection capable of conducting an aerosol, powder or liquid. Therefore, it would have been obvious to one of ordinary skill in the art to use inhaler of Hochrainer US'118 because

Hochrainer US'118 inhaler has structures (structures of inhaler as claimed) that can efficiently allow administration of power medicament.

**As to claim 12**, Hochrainer US'118 in figure 6 teaches the capsule chamber has a cross section 1.1 to 2.5 times as great as the capsule diameter and a length 1.02 to 2 times the length of the capsule.

**As to claim 13**, Hochrainer US'118 in column 3 lines 5-7 teaches "needles" as a cutting device. Although not labeled, two sharp spikes are shown in figure 6 inside button (10). Needles inherently have sharp spikes and/or cutters. Hochrainer US'118 in column 3 lines 7-10 teaches the spikes and/or cutters being capable of breaching the capsule chamber(s).

**As to claim 14**, Hochrainer US'118 in figure 6 shows the inhaler comprises: a) a cup-shaped lower part open at the top (6), b) a plate (8) which covers the opening of the lower part and perpendicularly to which is formed a pharmaceutical capsule chamber of the type described above (see capsules depicted in fig.6), a button (10) movable counter to a spring (11) on the capsule chamber. Hochrainer US'118 in column 3 lines 5-7 teaches "needles" as a cutting device. Although not labeled, two sharp spikes are shown in figure 6 inside button (10). Needles inherently have sharp spikes and/or cutters. Hochrainer US'118 in column 3 lines 7-10 teaches the spikes and/or cutters being capable of breaching the capsule chamber(s). Figure 6 further shows c) an upper part (13) with the mouthpiece which is connected to the capsule chamber so as to be able to convey a powder, aerosol or liquid, and d) a lid (15). Hinge apertures on the body of the cap (15) and lower part (6) allow elements a), b) c) and d) to be joined together by a common hinge element such that they can be moved back and forth relative to one another.

**As to claim 15**, Hochrainer US '118 in figure 6 shows the inhaler contains a magazine (see plurality of chambers (1) shown on plate (8) of capsule chambers (1).

**Claim 16 is rejected under 35 U.S.C. 103(a) as being obvious over Hochrainer et al US 5,947,118 in view of Hochrainer et al. US 2001/0008637.**

**As to claim 16**, Hochrainer US'118 in figure 6 shows an inhaler comprising an upper housing part (13) which is connected to a mouthpiece (12) and a lower housing part (6) with at least one capsule chamber (9), the capsule chamber(s) having an air inlet opening (14), and an air outlet opening (opening though the mouthpiece) connected to the mouthpiece, wherein at least one capsule chamber (9) is capable of accommodating a capsule having a longitudinal axis and a transverse axis which is shorter in relation to the longitudinal axis. Hochrainer US'118 in column 3 lines 4 and 5 discloses chamber (9) holds a capsule/composition. Hochrainer US'118 however lacks the features forming the outer contour are symmetrical with respect to a transverse plane that bisects the longitudinal axis and features cited in lines 7-10 that are being excluded from the conditions of symmetry. However, Hochrainer US '637 in figure 2a shows the features forming the outer contour of the capsule are symmetrical with respect to a transverse plane which bisects the longitudinal axis, except for angels of taper up to 5 ° (see bulge 5) on the body (3) of capsule, which is one of the features excluded form the conditions of symmetry in the claimed invention. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the capsule with capsule as taught by Hochrainer US'637 for the purposes of providing a capsule that can:

(1) better adapt to the special condition in a powder inhaler (see paragraph 8 of Hochrainer US'637), and (2) release entire content of the capsule (see paragraph 15 of Hochrainer US'637).

***Response to Arguments***

11. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHUMAYA B. ALI whose telephone number is (571)272-6088. The examiner can normally be reached on M-W-F 9 am - 5 pm.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shumaya B. Ali /  
Examiner, Art Unit 3771

/Justine R Yu/

Supervisory Patent Examiner, Art Unit 3771